

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

CIVIL ACTION NO: _____

ERICA INGALLS, Individually and as Mother
And Next Friend of B.I.¹,

Plaintiff,

v.

UNITED STATES OF AMERICA,

Defendant.

**ORIGINAL COMPLAINT FOR DAMAGES
UNDER THE FEDERAL TORT CLAIMS ACT**

JURISDICTION, VENUE AND CONDITIONS PRECEDENT

1. Plaintiff Erica Ingalls, mother and next friend of B.I., resides at 76 Union Street #1, Peterborough, New Hampshire 03458. B.I. also resides at 76 Union Street #1, Peterborough, New Hampshire 03458.
2. The claims herein are brought against the United States of America, pursuant to the Federal Tort Claims Act (28 U.S.C. §2671, *et seq.*) and 28 U.S.C. §§1346(b), for money damages as compensation for personal injuries that were caused by the negligent and wrongful acts and omissions of employees of the United States Government while acting within the scope of their offices and employment, under circumstances where the United States, if a private person, would be liable to the Plaintiffs in accordance with state law.
3. Venue is proper, pursuant to 28 U.S.C. §1402(b), as Plaintiffs are residents of New Hampshire.

¹ The minor child is referred to by his initials only in accordance with Fed. R. Civ. P. 5.2(a)(3).

- 2 -

4. Plaintiff has fully complied with the provisions of 28 U.S.C. §2675 of the Federal Tort Claims Act.
5. This suit has been timely filed, in that Plaintiff timely delivered to the Department of the Navy, Office of the Judge Advocate General, Tort Claims Unit Norfolk, SF-95 claim forms. In a letter dated November 6, 2012, the Department of the Navy acknowledged receipt of the claim forms on October 30, 2012.² On April 15, 2014, the Department of the Navy denied plaintiffs' SF-95 claims.
6. Consistent with the pertinent provision of the Federal Tort Claims Act (28 U.S.C. §2671, *et seq.*), Plaintiff submitted in her SF-95 claim forms demands for the sum of \$12,000,000 (twelve million dollars) on behalf of B.I. and the sum of \$6,000,000 (six million dollars) on behalf of Erica Ingalls.

THE FDA AND VACUUM ASSISTED DELIVERY DEVICES

7. On May 21, 1998, the Food and Drug Administration ("FDA") issued a "FDA Public Health Advisory: Need for CAUTION When Using Vacuum Assisted Delivery Devices" ("FDA Advisory").
8. The FDA Advisory was issued to obstetricians, birthing centers, nurse mid-wives, pediatricians, ultrasonographers, ObGyn nurses, family practitioners, radiologists, hospital risk managers, and hospital ObGyn departments.

² Plaintiff attempted to deliver the SF-95 forms on the Department of the Navy on October 29, 2012 but the Offices of the Judge Advocate General were closed due to Hurricane Sandy.

- 3 -

9. The purpose of the FDA Advisory was to advise medical or health care professionals that the vacuum assisted delivery devices could cause serious or fatal complications and to provide guidance to minimize the risks associated with the devices' use.
10. The FDA demonstrated concern that some health care professionals who used vacuum assisted delivery devices, or those who cared for these infants following delivery, were not aware that these devices may produce life-threatening complications.
11. Another concern of the FDA was that if health care professionals responsible for the care of neonates were not alerted when a vacuum assisted delivery device had been used on a particular infant, those professionals might not adequately monitor for the signs and symptoms of device-related injuries.
12. The FDA Advisory noted two major life-threatening complications following use of vacuum assisted delivery devices: subgaleal hematoma and intracranial hemorrhage, including subdural, subarachnoid, intraventricular and/or intraparenchymal hemorrhage.
13. The FDA Advisory offered that signs of intracranial hemorrhage could include indications of cerebral irritation, including convulsions, lethargy, obtundation, apnea, bulging fontanelle, poor feeding, increased irritability, bradycardia and/or shock, and that the signs and symptoms were sometimes delayed until several hours after birth.
14. The FDA Advisory recommended that persons who use vacuum devices for assisted delivery be versed in their use, and aware of the indications, contraindications and precautions as supported in the accepted literature and current device labeling, and that all persons using a vacuum device should read and understand the device's instructions, paying particular attention to the manufacturer's instructions regarding cup placement, vacuum

- 4 -

strength to be used, cumulative duration of applications and number of recommended extraction attempts.

15. The FDA Advisory further recommended that health care professionals, when using vacuum devices, apply steady traction in the line of the birth canal, while avoiding rocking movements or the application of torque to the device as dangerous.
16. The FDA Advisory recommended that all health care professionals responsible for the infant's care be made aware of the use of a vacuum device, so as to be on notice to monitor the infant for signs of complications.

FACTS

17. From April 8, 2010 through to and including October 31, 2010, plaintiff Erica Ingalls was married to Ryan Ingalls, an active service member in the United States Marine Corp.
18. From April 8, 2010 to October 31, 2010, Ms. Ingalls received medical care at the Naval Hospital at Camp Lejeune, North Carolina, including but not limited to treatment for her pregnancy, delivery and labor of her unborn son, B.I.
19. During her period of treatment from April 8, 2010 through October 31, 2010 at the Naval Hospital at Camp Lejeune, Ms. Ingalls was under the care of a number of physicians, nurses, midwives and other medical providers employed by the Department of Navy.
20. On or about October 28, 2010, Ms. Ingalls was admitted to the Naval Hospital at Camp Lejeune for management of her labor and the delivery of B.I.
21. On or about October 29, 2010, Ms. Ingalls gave birth to B.I. at the Naval Hospital at Camp Lejeune.

- 5 -

22. During the course of her labor and delivery of B.I., Ms. Ingalls was under the care of Camp Lejeune Naval Hospital medical and nursing staff, including but not limited to Ms. Ingalls' treating physician, Tanya Porter, M.D., a number of nurses and a mid-wife.
23. During the course of the delivery of B.I., Ms. Ingalls' treating physician, in the presence of and/or with assistance from others in the Camp Lejeune Hospital medical and nursing staff, employed one or more vacuum assisted delivery devices to extract B.I. from Ms. Ingalls' womb.
24. A day after his delivery, on October 30, 2010, B.I. experienced seizure activity, beginning at the left lower extremity and progressing to the entire body, and a caput, or knob-like protuberance, was discovered on the right side of his head secondary to the vacuum extraction. It was noted in the medical records that B.I. had "weird rhythmic movement in [his] extremities."
25. The medical staff at the Naval Hospital subsequently performed a CT scan, which showed a subdural hemorrhage along the tentorium, a non-displaced fracture of the occipital bone with depression and with diastasis of the lambdoid sutures bilaterally. The medical records also noted a "[d]ifficult vacuum delivery with shoulder dystocia."
26. In the absence of a neonatal intensive care unit at the Naval Hospital, and requiring emergency care, B.I. was airlifted to Pitt County Memorial Hospital, Greenville, North Carolina on October 31, 2010 for emergency treatment and evaluation until his discharge on November 5, 2010.
27. While at Pitt County Memorial Hospital, B.I. suffered additional seizures.
28. Upon information and belief:

- 6 -

- a) In the course of their management of Ms. Ingalls' labor and the delivery of B.I. on October 28 and 29, 2010, Ms. Ingalls' treating physician and/or others on the Camp Lejeune medical and nursing staff were negligent in the delivery of B.I., including, but not limited to, their negligent and improper use of a vacuum assisted delivery device in extracting B.I. from Ms. Ingalls' womb.
- b) Camp Lejeune's medical and nursing staff, including but not limited to Ms. Ingalls' treating physician, failed to properly assess, evaluate and manage the health of Erica Ingalls, and her unborn infant son, B.I., during the course of Ms. Ingalls' pregnancy and failed to recognize and account for evidence of fetal stress during labor and complications associated with the use of a vacuum assisted delivery device during the delivery of B.I.; failed to recognize the extent and degree of risk present to mother and fetus; and failed to otherwise appropriately manage the pregnancy and labor of Ms. Ingalls and the delivery of B.I.
- c) As a result of the negligence of the Naval Hospital medical and nursing staff and personnel, B.I. experienced a traumatic vacuum assisted delivery, which resulted in serious complications and physical injuries, including a skull fracture, a subdural hematoma along the tentorium, shoulder dystocia, seizures which required medication, treatment and hospitalization, and what are likely to be lifelong, devastating injuries.
- d) As a result of the negligence of the Naval Hospital medical and nursing staff and personnel, B.I. already has exhibited a significant spoken language delay, and his likelihood of future seizures is elevated. B.I.'s prognosis, his ability to speak and his

- 7 -

cognitive function at his young age remains guarded and uncertain. B.I. is receiving, and will continue receiving for the immediate future, therapy aimed at trying to improve his ability to express himself as other children his age do – with language.

- e) As a result of the negligence of the Naval Hospital medical and nursing staff and personnel, Erica Ingalls suffered, and will continue to suffer, loss of filial consortium and emotional and mental anguish, and has incurred, and will continue to incur, medical and other expenses for herself and for her son.

29. Upon information and belief:

- a) B.I. experienced a traumatic vacuum-assisted delivery, which resulted in a skull fracture, subdural hemorrhage and ultimately seizures;
- b) As a result, B.I.'s likelihood of having seizures in the future is elevated compared to other children without a history of neonatal seizures or intracranial hemorrhage;
- c) Given B.I.'s current young age, his development must be monitored and tested and, as an "at risk" individual, he should continue to receive therapeutic support;
- d) B.I. has significant spoken language delay, the etiology of which would include the brain injury he suffered as a newborn.

COUNT I

(B.I.'s Medical Negligence Claim against United States)

- 30. The plaintiff hereby incorporates by reference each allegation contained in paragraphs 1 through 29.

- 8 -

31. The defendant, United States of America, acting by and through its servants, agents and/or employees at the Naval Hospital at Camp Lejeune, had a duty to possess the degree of knowledge or skill possessed by, and to exercise the degree of care ordinarily exercised by, a reasonably skilled, careful, and prudent health care practitioner engaged in a similar practice under the same or similar circumstances.
32. Upon information and belief, the defendant's servants, agents and/or employees at the Naval Hospital, Camp Lejeune, either lacked the requisite degree of knowledge or skill, or failed to exercise that degree of care, in the course of their treatment of Erica Ingalls and her unborn son, B.I. The Camp Lejeune Naval Hospital medical and nursing staff's failure to meet the standard of care includes, but is not limited to, the negligent and/or improper vacuum extraction of B.I. from the womb; Camp Lejeune's medical and nursing staff's failure to properly assess, evaluate and manage the health of Erica Ingalls, and her unborn infant son, B.I., including the failure to recognize and respond to evidence of fetal stress, and to the complications associated with vacuum assisted delivery devices; and Camp Lejeune's medical and nursing staff's failure to otherwise appropriately manage the pregnancy and labor of Erica Ingalls and the delivery of B.I.
33. Upon information and belief, as a direct and proximate result of the Naval Hospital medical and nursing staff's failure to meet the standard of care, B.I. suffered physical injury and developmental complications, including a significant spoken language delay, in addition to yet unknown and/or undiagnosed injuries and permanent impairments.
34. Upon information and belief, as an additional result of Naval Hospital, Camp Lejeune, medical and nursing staff's negligence, B.I. has suffered and will continue to experience

- 9 -

permanent impairment, emotional distress and loss of enjoyment of life. He will also incur medical and therapy expenses and other extraordinary costs and will suffer a diminution in his earning capacity.

35. Plaintiff objects to the pre-filing requirements of N.C.R. Civ. P. 9(j) as unconstitutional. Rule 9(j) effectively requires plaintiffs to provide their case before factual discovery is even begun, denies malpractice plaintiffs their rights of due process of law, of equal protection under the law, of the right to open courts, and of the right to a jury trial, in violation of the Seventh and Fourteenth Amendments of the United State Constitution; Article I, sections 6, 18, 19, 25 and 32, and Article IV, sections 1 and 13, of the North Carolina Constitution; and Part One, Articles 1, 2, 20, and 37, and Part Two, Articles 4 and 72-a, of the New Hampshire Constitution.
36. Without waiving these objections, Plaintiff asserts that the medical care, or lack thereof (including that given by Defendant's servants, agents and/or employees), which is the subject of this action has been reviewed by a person reasonably expected to qualify as an expert witness under Rule 702 of the North Carolina Rules of Evidence who is willing to testify that the care did not comply with the applicable standard of care.
37. Wherefore, Plaintiff demands judgment against the Defendant, United States of America, for an amount no less than \$12,000,000, plus interest and costs.

COUNT II

(Erica Ingalls' Claim against United States)

38. The Plaintiff hereby incorporates by reference each allegation contained in paragraph 1 through 37.

- 10 -

39. Upon information and belief, as a direct and proximate result of the defendant's negligence as set forth above, Erica Ingalls contemporaneously perceived her son's injuries, his suffering and his developmental complications and she has experienced and will continue to experience severe emotional distress.
40. Upon information and belief, as a further direct and proximate result of the defendant's negligence, Erica Ingalls has and will continue to experience a loss of filial consortium with her minor son, B.I.
41. Wherefore, Erica Ingalls demands judgment against the Defendant, United States of America, for an amount no less than \$6,000,000, plus interest and costs.

Respectfully Submitted,

Dated: August 7, 2014

Plaintiffs,
Erica Ingalls, Individually and as
Mother and Next Friend of B.I.,
By their attorneys,

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